IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

MARK J. LELONEK, Plaintiff, **v.** BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., Defendant.	)	**CASE NO. 3:20cv00378** **COMPLAINT AND DEMAND FOR JURY TRIAL**

The Plaintiff, Mark J. Lelonek, files this Complaint and Demand for Jury Trial against Defendant, Boehringer Ingelheim Pharmaceuticals, Inc., alleging as follows:

BACKGROUND

1. Plaintiff Mark J. Lelonek ("Lelonek" or "Plaintiff") is a resident of Lac du Flambeau, Wisconsin, located in Vilas County.

2. Defendant BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. ("Boehringer" or "Defendant") is a pharmaceutical corporation incorporated and existing under the laws of the State of Delaware. Boehringer is not authorized to do business in Wisconsin and therefore may be served with process by registered or certified mail, return receipt requested, addressed to the corporation at its principle place of business, pursuant to W.I. Legislature §180.0504.

3. At all times relevant to this Complaint, the Defendant was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into

interstate commerce, either directly or indirectly through third parties or related entities, the prescription anticoagulant drug sold under the name Pradaxa® throughout the State of Wisconsin.

JURISDICTION AND VENUE

4. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds $75,000, exclusive of interest and cost, and because, among other reasons, Defendant has significant contacts with this district by virtue of doing business within this judicial district.

5. Venue is proper within this district pursuant to 28 U.S.C. § 1391 because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL ALLEGATIONS

[Background of the Case]

6. At all relevant times, Boehringer, directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested, and sold Pradaxa®.

7. Pradaxa® is the trade name for the drug dabigatran etexilate mesylate. Pradaxa® was the first oral anticoagulation medication approved in the U.S. in more than 50 years for patients with non-valvular atrial fibrillation. Pradaxa® was the first in a class of drugs colloquially referred to as New/Novel Oral Anticoagulants ("NOAC") or Direct Oral Anticoagulants (DOAC"). Prior to the United States Food and Drug Administration's ("FDA") approval of Pradaxa®, warfarin (brand name Coumadin®) was the only oral anticoagulant available in the U.S. for reducing stroke and systemic embolism in patients with atrial fibrillation. Warfarin is a vitamin K antagonist. Warfarin works by inhibiting the production of vitamin K, which is required for the activation of

various clotting factors. The resultant effect of Warfarin is that the blood is "thinned" and takes longer to clot. Warfarin's effect is best measured by the laboratory test Prothrombin Time ("PT"). PT results are reported in seconds (time to clot formation). Because PT reagents vary by manufacturer and even by lot number, and because different analyzers define clot formation differently, PT results cannot be reliably compared from lab to lab or even within one laboratory over time. To address this variability issue, an international standard was defined so that all PT results could be correlated to an international standard expressed as a ratio called the International Normalized Ratio ("INR"). Through the INR, PT results can be compared across PT reagents, analyzers and laboratories. The general targeted INR for non-valvular atrial fibrillation patients taking warfarin is 2.5 with an accepted range of 2–3. This target is maintained by frequent (usually monthly) periodic blood testing (PT/INR) and dose adjustments of warfarin when indicated.

8. For marketing and financial reasons and prior to conducting any clinical trials, Boehringer predetermined that Pradaxa® would be marketed as the first oral anticoagulant that did not require routine blood monitoring. "No monitoring" became Boehringer's mantra.

9. Pradaxa® is a prodrug, which means it is not biologically active until it is cleaved/metabolized into the active ingredient, dabigatran.

10. As a result, Boehringer designed Pradaxa's® Phase 3 clinical trials with no dose adjustments, regardless of how over or under-anticoagulated Pradaxa® patients were. Given this development process, Boehringer submitted its New Drug Application for Pradaxa® to the FDA without instructions for monitoring dabigatran plasma concentrations ("Pradaxa® Levels") or any valid means by which physicians could otherwise assess the anticoagulant effects in Pradaxa® users.

11. Dabigatran is not absorbable in the gut when orally administered. In order to make dabigatran bioavailable/absorbable, an orally absorbable mesylate salt form of etexilate had to be added hence the name dabigatran etexilate mesylate.

12. Even then, dabigatran etexilate was so poorly absorbed that Boehringer had to coat its drug with tartaric acid in order to lower the PH in the stomach to raise the absorption rate. In healthy subjects the bioavailability of Pradaxa® is just 3–7 percent meaning only a small percentage of the drug makes its way into a patient's blood stream.

13. By comparison, the bioavailability of warfarin is essentially 100%, and the bioavailability of the second FDA approved NOAC, Xarelto, is 80%. Hence, increases in absorption of Pradaxa®, unlike other anticoagulants, results in a large increase in the "thinning" of the patient's blood.

14. On October 19, 2010, Pradaxa® was approved by the FDA to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. The FDA approved two dosages: 75 mg and 150 mg, to be taken twice daily ("BID").

15. The 75 mg dose was approved for patients with severe renal impairment. Its approval was based on pharmacometric modeling not human clinical trial data. Boehringer knew that because dabigatran is largely cleared by the kidneys that patients with severe renal impairment would be excessively anticoagulated if prescribed the 150 mg dose of Pradaxa®. The 75 mg dose of Pradaxa® has never been tested in any clinical trials, let alone clinical trials of atrial fibrillation patients with severe renal impairment—the indicated population for the dose.

16. On April 4, 2014, Pradaxa® was approved by the FDA for the treatment of deep venous thrombosis ("DVT") and pulmonary embolism ("PE") in patients who had been treated with parenteral anticoagulation for 5 to10 days.

17. Additionally, the FDA approved Pradaxa® to reduce the risk of recurrence of DVT and PE in patients who had been previously treated.

18. The Randomized Evaluation of Long-Term Anticoagulation Therapy ("RE-LY") clinical trial was the pivotal trial for the approval of Pradaxa® by the FDA for stroke prevention in atrial fibrillation patients. The FDA granted approval for Pradaxa's® atrial fibrillation indication on October 19, 2010. RE-LY studied just over 18,000 patients in three arms: Warfarin, Pradaxa® 110 mg BID, and Pradaxa® 150 mg BID.

19. The RE-LY trial measured dabigatran plasma concentrations ("Pradaxa® Levels") on over 9,000 Pradaxa® patients in the study. Despite collecting extensive data on Pradaxa® Levels, Pradaxa® was not dose adjusted no matter what Pradaxa® Level was found.

20. Because dabigatran that has been absorbed and is circulating in the blood, i.e., systemic dabigatran, is 80% cleared by the kidneys, renally impaired patients with an estimated creatinine clearance of less than 30 ml/min using the Cockcroft-Gault formula ("Cockcroft formula") were excluded from the RE-LY trial.

Boehringer's Over Promotion of Pradaxa®

21. Boehringer's marketing campaign and materials promoted Pradaxa® as: a) more effective than warfarin in preventing stroke and systemic embolism; and b) a more convenient alternative to warfarin therapy because Pradaxa® allegedly does not require: dose adjustments; dietary restrictions; monitoring of either Pradaxa® Levels or anticoagulation status; and only has two drug/drug interactions that may require dose adjustment.

22. Boehringer spent significant money in promoting Pradaxa®, including $67,000,000 spent during 2010 alone (although Pradaxa® was not approved for sale until October 19, 2010).

23. During 2011, Boehringer reportedly undertook 1.5 million Pradaxa® "detailing sessions", i.e., marketing/sales visits by Boehringer's sales force, with U.S. primary care physicians, internists, group practitioners, cardiologists, and nurses, spending approximately $464,000,000 during this 12-month period to promote Pradaxa® in the U.S.

24. As part of Boehringer's marketing of Pradaxa®, Boehringer widely disseminated false and misleading direct-to-consumer advertising campaigns designed to influence patients, including Plaintiff, to make inquiries to their prescribing physicians about Pradaxa® and/or request prescriptions for Pradaxa®.

Negligent and Fraudulent Misrepresentations

Regarding Coagulation Assessments

25. Boehringer, at all relevant times, has marketed Pradaxa® as providing a predictable level of anticoagulation that would be within a wide therapeutic range, which results in patients being appropriately anticoagulated when Pradaxa® is prescribed according to Boehringer's U.S. Pradaxa® label.

26. After FDA approval of Pradaxa®, however, Boehringer's continued analysis of data from the RE-LY trial revealed many patients were either under or over-anticoagulated when dosed according to the U.S. Pradaxa® label. Boehringer has never advised physicians of this fact.

27. Boehringer's U.S. Pradaxa® label does not advise physicians that there is a close linear relationship between the amount of dabigatran in a patient's blood (Pradaxa® Level) and the level of anticoagulation the patient experiences as a result of having taken Pradaxa®.

28. Boehringer also does not tell physicians at what Pradaxa® Level a Pradaxa® patient is exposed to an increased/excessive/unreasonable risk of bleeding caused by excessive dabigatran exposure.

29. Boehringer tells U.S. physicians in its U.S. Pradaxa® label that "the aPTT (activated partial thromboplastin) test provides an approximation of Pradaxa's® anticoagulant activity."

30. The aPTT test is a laboratory coagulation study that is prolonged by the impairment/reduction of clotting factors along the intrinsic and common pathways (factors I, II, V, VIII, IX, X, XI, XII) only one of which is affected by Pradaxa® (factor II). Given aPTT's lack of specificity (and aPTT variability as discussed below), aPTT is not an appropriate tool to monitor Pradaxa's® anticoagulant effect. The aPTT test is approved by the FDA to monitor the anticoagulant effect of heparin, an injectable anticoagulant.

31. The aPTT test has never been approved by the FDA to monitor the anticoagulant effect of Pradaxa®.

32. Boehringer's U.S. Pradaxa® label tells physicians the range of trough (values measured 10 to 16 hours after a patient's last dose) aPTT in the RE-LY trial was from 40–76 seconds (for patients in the 10^{th} to 90^{th} percentiles). The implication being that patients within this range are appropriately anticoagulated.

33. Boehringer's U.S. Pradaxa® label does not inform physicians that those aPTT values were based on a specific aPTT reagent/test, aPTT reagent manufactured by Roche Diagnostics GmbH Mannheim, Germany, or that this reagent has never been marketed in the U.S.

34. Dr. Joanne VanRyn, a scientist at Boehringer who has published in the field of laboratory testing with respect to Pradaxa®, testified that Boehringer utilized this "in-house" reagent because it was particularly sensitive to dabigatran.

35. Dr. VanRyn also testified that because of aPTT reagents' sensitivity to dabigatran varies greatly, it is "critical" that a physician knows what aPTT reagent was used in interpreting the results in a patient treated with Pradaxa®.

36. Boehringer has never attempted to inform physicians that it is critical for physicians to know which aPTT reagent was used by the laboratory doing the aPTT study on their patients in order to properly interpret aPTT results.

37. Boehringer has never adequately informed physicians that the aPTT reagent used in the RE-LY trial yields qualitatively different results than reagents used by laboratories in the US.

38. For example, a patient in the U.S. with a trough aPTT of 76 seconds as measured by a commonly used aPTT reagent in the U.S., Actin FSL, would likely have a Pradaxa® Level of over 650 ng/mL, well above the 90th percentile (215 ng/mL) seen in the RE-LY trial; a clearly excessive amount.

39. Boehringer also represents to physicians in its U.S. Pradaxa® label that "The degree of anticoagulant activity can also be assessed by the ecarin clotting time (ECT)." Boehringer makes this representation even though:

a. ECT is not available clinically to physicians in the U.S.;

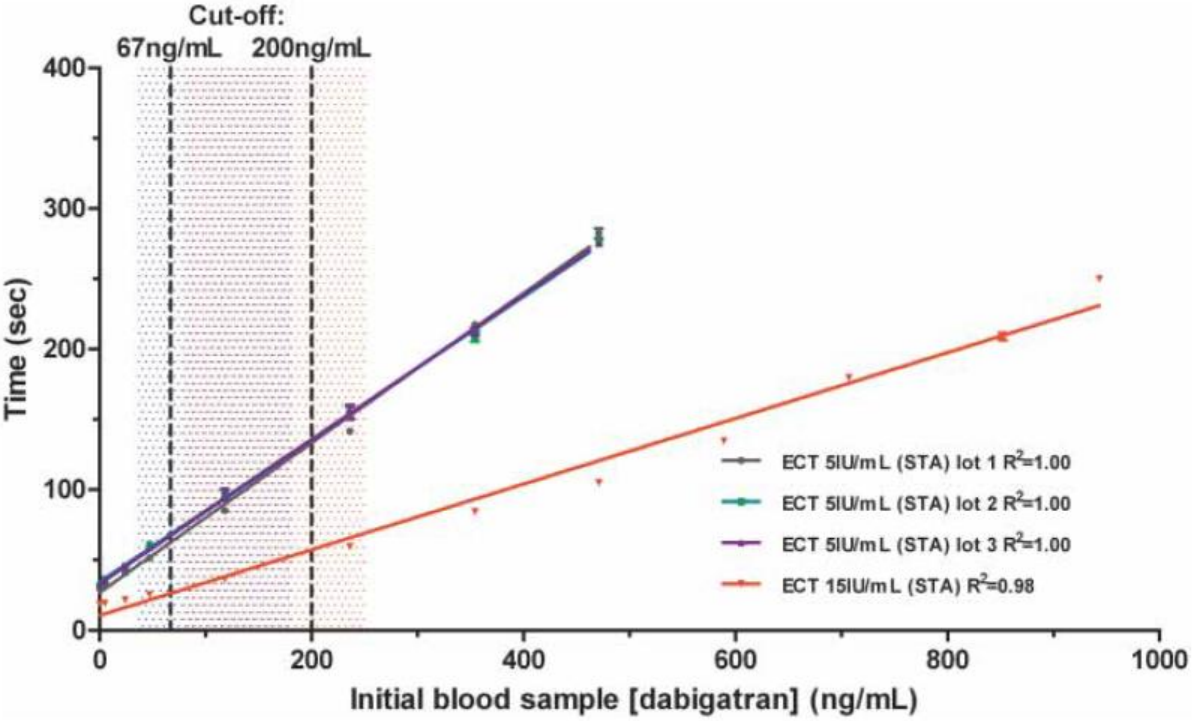
b. ECT is not approved by the FDA for any purpose;

c. ECT is not approved by the FDA to assess the anticoagulant activity of Pradaxa® in patients; and

d. There is no standard methodology for performing ECT.

40. Boehringer's U.S. Pradaxa® label also states that the median and 10th to 90th percentile trough ECT in the RE-LY trial was 63 and 44-103 seconds, respectively. Boehringer, however, did not disclose the method by which the ECT test was performed.

41. Douxfils et al. published a study in 2012[1] that proved this point. Figure 4 from the publication (reproduced below for convenience) shows the dramatically variable results from two common ECT methods when run on plasma samples spiked with known quanities of dabigatran:



As demonstrated from this figure, an ECT result of 50 seconds using one method would reflect an under anticoagualated patient while using the other method would reveal a patient was over anticoagulated.

[1] Douxfils, J., F. Mullier, S. Robert, C. Chatelain, B. Chatelain, and J. M. Dogne. "Impact of Dabigatran on a Large Panel of Routine or Specific Coagulation Assays. Laboratory Recommendations for Monitoring of Dabigatran Etexilate." *Thromb Haemost* 107 (2012). https://doi.org/10.1160/TH11-11-0804.

42. 21 C.F.R. § 201.57 requires manufacturers like Boehringer to include in their U.S. labels "any laboratory tests helpful in following the patient's response" to their drugs.

43. Despite Boehringer's knowledge of laboratory tests that can provide accurate quantitative assessments of a patient's Pradaxa® Levels, and therefore the anticoagulant effect of Pradaxa®, Boehringer has failed to disclose such tests in its U.S. label.

44. These tests include, but are not limited to:

a. Diluted thrombin time (a/k/a Hemoclot) (a test Boehringer recommends in its labels in other countries);

b. Calibrated Russell's Viper Venom;

c. Calibrated Ecarin Clotting Time;

d. Liquid chromatography/tandem mass spectrometry (LC/MS-MS); and

e. Ecarin Chromogenic Assay.

45. Boehringer also failed to inform physicians that national laboratories LabCorp and Quest Laboratories, available to all of Plaintiff's physicians, have offered Pradaxa® level tests since at least 2013.

46. As a result of Boehringer's failure to properly inform physicians of these facts, Plaintiff's physicians are unaware that laboratory tests are available to assess their patients' Pradaxa® Levels or that there is a need to assess Pradaxa® Levels.

47. The ***diluted*** thrombin time was created because the *standard* thrombin time study is "exquisitely sensitive" to dabigatran; meaning that even therapeutic Pradaxa® Levels will cause a standard thrombin time study to exceed its maximum range. Thus, a standard thrombin time test is not useful to quantify Pradaxa® Levels, a standard thrombin time study in the normal range confirms a Pradaxa® patient is safe to operate on from a coagulation standpoint. Accordingly,

thrombin time is another useful laboratory test that Boehringer fails to include in its U.S. Pradaxa® label.

Regarding Kidney Function

48. Boehringer's U.S. Pradaxa® label advises physicians to reduce the prescribed dose of Pradaxa® to 75 mg BID for patients with severe renal impairment (creatinine clearance from 15 to 30 ml/min).

49. True creatinine clearance measures the creatinine in a patient's urine collected for 24 hours and from the patient's blood to determine the rate at which creatinine is being cleared from the blood. Physicians, however, do not order 24-hour creatinine clearance studies, rather they use estimated creatinine clearance as a surrogate for the actual measurement. There are multiple formulas for estimating creatinine clearance.

50. Boehringer, unfortunately, does not tell physicians that all of the information about kidney function and creatinine clearance, including dosing recommendations, contained in its U.S. Pradaxa® label are based on the Cockcroft formula.

51. The National Kidney Foundation has determined that the Cockcroft formula yields inaccurate results and should NOT be used for drug dosing or to estimate kidney function for clinical use.

52. U.S. laboratories report estimated kidney function based on formulas *other than* Cockcroft formula.

53. Prescribing physicians in the U.S. use the estimated creatinine clearance provided by laboratories when making dosing decisions about Pradaxa®.

54. Boehringer has not informed physicians that the formulas used by U.S. laboratories to estimate kidney function often yield significantly different results that the Cockcroft formula.

55. Boehringer's failure to inform physicians of these facts results in some patients receiving too much or too little Pradaxa® when taking the dose recommended by the Pradaxa® label.

56. After FDA approval of Pradaxa®, Boehringer recognized the need to provide guidance to physicians and solicited a proposal to evaluate the RE-LY trial data using modern methods of estimating creatinine clearance so that appropriate guidance could be offered to physicians.

57. Despite being told such an analysis could be done with the data already collected, Boehringer refused to conduct or retain others to perform such an analysis.

Therapeutic Range of Pradaxa® Levels

58. On March 7, 2011, scientists at Boehringer issued an official Clinical-Overview Statement (Document Number U11-1855-01) Titled: "Pradaxa® prescriber guide reference document – Derivation of limits in coagulation tests as given in Pradaxa® prescriber guides for SPAF and VTEp" (hereinafter referred to as "Report 1855").

59. Report 1855 is Boehringer's official assessment of various laboratory anticoagulation studies as they relate to Pradaxa® patients.

60. When a foreign health regulator questioned Boehringer's determination that a Pradaxa® Level of 200 ng/mL was the "do not exceed value" for safety concerns, Boehringer provided Report 1855 as support for the value. Notably, however, Boehringer has never provided Report 1855 analysis to the FDA.

61. In Report 1855, Boehringer admits that a diluted thrombin time of 65 seconds corresponds to a Pradaxa® Level of 215 ng/mL which is a "conservatively assessed cut-off value" to avoid unnecessary bleeding risks.

62. Furthermore, Report 1855 determines that "an assessment of the risk of bleeds in a given patient should be based on the actual dabigatran concentration [Pradaxa® Level] …."

63. Separately, a few days later, Boehringer's statistician, Dr. Helmut Schumacher, reported the results of an analysis he conducted demonstrating a therapeutic range for Pradaxa® trough Levels. Dr. Schumacher's analysis reflected that trough Pradaxa® Levels could be broken down into three groups (measured in ng/mL): <30; 30 to <150; and 150 and greater). Dr. Schumacher found that for Plasma Levels below 30 ng/mL stroke risks rose sharply, but that for Plasma Levels above 30 ng/mL there was no significant rise in stroke risks. Likewise, Dr. Schumacher's analysis revealed that at Pradaxa® Levels above 150 ng/mL there is clearly increased bleeding risks but no significant difference in the two groups below 150 ng/mL. The obvious conclusion from this analysis and the one reached by Dr. Schumacher is: "a Pradaxa® level between 30 and 150 appears to [be] optimal regarding both, prevention of ischemic stroke and avoidance of bleed;" hence a therapeutic range. This analysis was never provided to the FDA.

64. On October 27, 2011, the FDA advised Boehringer that approval of another dose of Pradaxa® (110 mg) would "best be served" with some type of monitoring and suggested that Boehringer conduct a relatively simple study in which Boehringer identified patients on Pradaxa® 150 mg BID that had Pradaxa® Levels in the top third (1/3) of the population and reduced their dose to 110 mg and, if needed, to 75 mg to demonstrate that those patients initially with the top third (1/3) Pradaxa® Levels could be reduced to the middle third of Pradaxa® Levels.

65. This suggestion by the FDA was contrary to Boehringer's "no monitoring" mantra, and after assessment, Boehringer determined that better results would be obtained by dose adjusting using only the 75 mg and 150 mg doses; hence, Boehringer never pursued the study recommended by the FDA.

66. Between January and September of 2012, Boehringer's pharmacometric modeling expert, Dr. Thorsten Lehr, performed "extensive and comprehensive clinical trial simulation analyses" of 500 randomized clinical trials of 5,000 patients, each to determine if assessing Pradaxa® Levels and dose adjusting Pradaxa® would be beneficial. The results were clear: a significant 21% reduction in major bleeds while maintaining stroke protection. This dose adjusting analysis, however, was never provided to the FDA.

67. An article published in the February 4, 2014, edition of the Journal of the American College of Cardiology[2] by Boehringer employees and others on behalf of the RE-LY Investigators (the "Reilly Lehr Paper") provided additional evidence, consistent with Report 1855 and Dr. Schumacher's analysis, of a therapeutic range for Pradaxa® Levels. The Reilly Lehr Paper revealed that Pradaxa® did not, in fact, have predicable levels in atrial fibrillation patients as Boehringer's marketing suggests. The Reilly Lehr Paper, even according to Boehringer's own experts retained for litigation, shows:

a. Patients in the RE-LY trial had trough Pradaxa® Levels which varied from 1 to over 800 ng/mL, i.e., over 800-fold variability;

b. The risk of major bleeding doubled at a Pradaxa® Level of 210 ng/mL compared to the mean Pradaxa® Level of 88 ng/mL;

c. The risk of stroke increased by 50% at a trough Pradaxa® Level of 28 ng/mL compared to the mean;

[2] Reilly PA, et al.; *RE-LY Investigators; The effect of dabigatran plasma concentrations and patient characteristics on the frequency of ischemic stroke and major bleeding in atrial fibrillation patients: the RE-LY Trial (Randomized Evaluation of Long-Term Anticoagulation Therapy)*; J Am Coll Cardiol 2014 Feb 4:63(4):321-8; http;//doi.org/10.1016/j.jacc.2013.07.104.

d. While the risk of major bleeding events increased significantly at all Pradaxa® Levels, the stroke protection provided by Pradaxa® only increased significantly up to a Pradaxa® Level of approximately 50 ng/mL; and

e. Ten percent (10%) of patients in the RE-LY trial had trough Pradaxa® Levels of less than 40 ng/mL and ten percent (10%) had Pradaxa® Levels in excess of 215 ng/mL. Accordingly, twenty percent (20%) of Pradaxa® patients have dangerous Pradaxa® Levels.

The Need to Assess Pradaxa® Levels

68. Boehringer directs physicians to dose Pradaxa® based on a patient's estimated creatinine clearance even though Boehringer knows:

a. All formulas used to estimate creatinine clearance are unreliable estimates of kidney function;

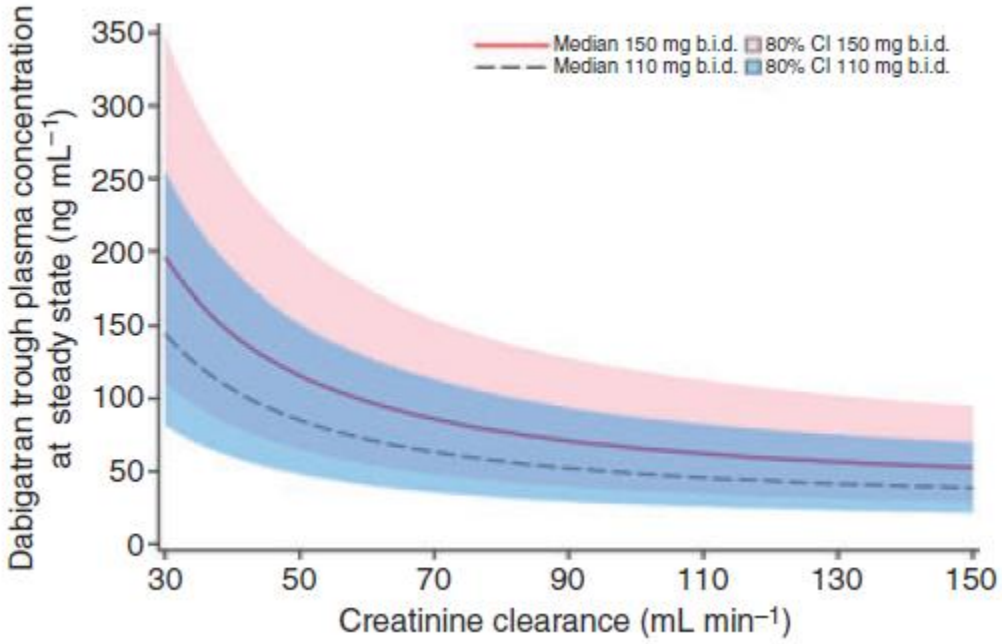
b. All formulas used to estimate creatinine clearance are based primarily on a measure of serum creatinine;

c. Serum creatinine levels are affected by many factors other than kidney function, which include, but are not limited to, body composition, exercise, hydration status, red meat consumption, and recent injuries;

d. There is tremendous variability in Pradaxa® Levels in patients with the same creatinine clearance. In a study published after FDA approval, Boehringer researchers (with some outside researchers) published a paper in which this issue was explored[3]. Figure 3 from that paper shows the tremendous variability in trough

[3] Liesenfeld, K.-H., T. Lehr, C. Dansirikul, P. A. Reilly, S. J. Connolly, M. D. Ezekowitz, S. Yusuf, L. Wallentin, S. Haertter, and A. Staab. "Population Pharmacokinetic Analysis of the

Pradaxa® Levels seen at various estimates of creatinine clearance when other factors affecting Pradaxa® Levels are controlled for:



It should be noted that these curves reflect on the 80th percentile. Ten percent (10%) of patients would have lower and ten percent (10%) of patients would have higher Pradaxa® Levels than that demonstrated on this graph. Additionally, this graph is based on a typical male with no comedications. Accordingly, estimated creatinine clearance cannot reliably estimate a patient's exposure to Pradaxa® 150 mg BID.

69. Boehringer knows that drugs classified as p-glycoprotein inhibitors ("p-gp inhibitors") can significantly increase Pradaxa® Levels. Boehringer's U.S. Pradaxa® label specifically advises physicians:

> In patients with moderate renal impairment (CrCl 30-50 mL/min), reduce the dose of PRADAXA® to 75 mg twice daily when administered

Oral Thrombin Inhibitor Dabigatran Etexilate in Patients with Non-Valvular Atrial Fibrillation from the RE-LY Trial." *Journal of Thrombosis and Haemostasis: JTH* 9, no. 11 (November 2011): 2168–75; https://doi.org/10.1111/j.1538-7836.2011.04498.x.

> concomitantly with the P-gp inhibitors dronedarone or systemic ketoconazole. The use of the P-gp inhibitors verapamil, amiodarone, quinidine, clarithromycin, and ticagrelor does not require a dose adjustment of PRADAXA®. T*hese results should not be extrapolated to other P-gp inhibitors [see Warnings and Precautions (5.5), Use in Specific Populations (8.6), and Clinical Pharmacology (12.3)]*.

70. While Boehringer promotes Pradaxa® as not having drug/drug interactions like warfarin, Boehringer fails to advise physicians about the dozens of commonly prescribed p-gp inhibitors that can affect Pradaxa® Levels. These p-gp inhibitors have been enumerated in studies published after approval both in peer reviewed literature and by the University of Washington Medical School.

71. Even Boehringer's retained litigation expert, Harvard Cardiologist Dr. Paul Zei, testified that when he prescribes the p-gp inhibitor Coreg to a Pradaxa® patient, Dr. Zei warns the patient that Coreg may increase the patient's Pradaxa® Level and increase bleeding risk.

72. Boehringer knows the use of p-gp inhibitors in patients combined with impaired kidney function will result in greater Pradaxa® Levels compared to that seen with either factor alone.

73. Boehringer is also aware that females on average have 30% higher Pradaxa® Levels than males.

74. Boehringer is also aware that patients over the age of 75 have higher Pradaxa® Levels than those under the age of 65.

75. Boehringer is also aware that after the age of 80 the risk benefit analysis favors warfarin over Pradaxa®.

76. As noted above, Boehringer's U.S. Pradaxa® label reports the bioavailability of Pradaxa® to be three percent (3%) to seven percent (7%; a potential difference of up to two hundred thirty-three percent (233%). In truth, Boehringer's internal studies demonstrate that in

small samples of healthy volunteers bioavailability ranged from .823% to 23.9%; difference in bioavailability of over two thousand eight hundred percent (2800%).” As Boehringer’s Dr. Paul Reilly wrote in August of 2011, “The wild card in all this is absorption…if you get someone who absorbs 50 percent instead of 6 percent, then this 10 times increase in plasma concentrations has created a condition that may be extremely risky for anyone who is old and frail.”

77. Boehringer knows that Pradaxa® Levels are the only way to assess both the risks and the benefits a patient will receive from taking Pradaxa®.

78. Boehringer knows that Pradaxa® Levels cannot be reliably estimated in an individual patient like Plaintiff.

79. Boehringer knows that the only way Plaintiff’s physicians could have assessed Plaintiff’s Pradaxa® Level was to order a laboratory test capable of providing an accurate assessment of his Pradaxa® Level.

Failure To Warn/Instruct

80. Prior to Plaintiff’s prescription of Pradaxa®, Plaintiff’s physicians received materials and information from Boehringer promoting Pradaxa® as described herein. Although Boehringer made periodic updates to the U.S. Pradaxa® label, including those made in March 2011, November 2011, January 2012, April 2012, May 2012, November 2012, December 2012, April 2013, December 2013, April 2014, August 2014, September 2014, January 2015, September 2015, October 2015, November 2015, and most recently in March 2018; each and every label has been defective, and Boehringer has been negligent for failing to:

a. Inform physicians that Pradaxa® Levels are closely correlated to the anticoagulant effect of Pradaxa® on an individual patient;

b. Inform physicians that assessing Pradaxa® Levels is the only way to determine the bleeding risk in an individual patient as a result of his exposure to Pradaxa®;

c. Inform physicians that without assessing Pradaxa® Levels, approximately twenty percent (20%) of all Pradaxa® patients will be either excessively anticoagulated or under-anticoagulated;

d. Inform physicians that Boehringer has determined Pradaxa® Levels at which a patient's bleed risk is excessive and unnecessary;

e. Inform physicians that Boehringer has identified a conservatively assessed cut off or "do not exceed" value for Pradaxa® Levels;

f. Inform physicians how to determine which Pradaxa® patients dosed according to its U.S. Pradaxa® label are receiving too much or too little Pradaxa® via a simple blood test;

g. Inform physicians that measuring a patient's Pradaxa® Level in the presence of additional risk factors for bleeding (and/or risk factors for increased Pradaxa® Levels) provides clinically useful information concerning whether Pradaxa® has a positive benefit-risk balance for a particular patient;

h. Inform physicians that there is a Pradaxa® Level range for Pradaxa® that provides effective stroke prevention while minimizing unnecessary bleed risk;

i. Inform physicians that personal characteristics (e.g., renal function, age, gender, weight) and concomitant medications (e.g., P-gp inhibitors) impact a patient's Pradaxa® Level in amounts that cannot be accurately predicted absent a blood test;

j. Inform physicians that patient characteristics (e.g., gastroesophageal reflux disease, thrombocytopenia, platelet defects, recent biopsies of the GI tract, esophagitis, etc.)

elevate bleed risk for patients taking Pradaxa® and that patient characteristic information is an important part of a risk-benefit assessment of Pradaxa® for a particular patient;

k. Inform physicians that increasing Pradaxa® Levels results in higher bleeding risk without a statistically significant increase in stroke protection above a Pradaxa® Level around 35 ng/mL;

l. Inform physicians that Pradaxa® Levels can and should be measured in patients;

m. Inform physicians that laboratory studies are available to identify patients who are at an increased risk of bleeding or stroke;

n. Provide adequate warnings and information regarding the true safety risks associated with the use of Pradaxa®;

o. Instruct physicians and laboratories about proper methods to determine a patient's Pradaxa® Levels;

p. Provide adequate warnings and information regarding the Pradaxa® Level below which a patient would not be receiving adequate anticoagulation to prevent embolic events, including strokes;

q. Provide adequate warnings and information regarding the Pradaxa® Level at which a patient's risk of major bleeding becomes unnecessary and/or excessive;

r. Provide adequate warnings, information and instructions regarding the use of appropriate laboratory tests: diluted thrombin time ("dTT"), calibrated ecarin clotting time ("ECT"), ecarin chromogenic assay, and/or calibrated Russell's viper venom to assess Pradaxa® Levels/anticoagulant effect of Pradaxa®;

s. Refrain from misleading physicians, including Plaintiff's physicians, to believe the blood clotting tests, aPTT and/or ECT could reasonably assess the anticoagulant effect of dabigatran on an individual by providing misleading expected ranges in the U.S. Pradaxa® Label;

t. Inform physicians and laboratories that aPTT results vary widely depending on the reagent used in the test and that aPTT should not be used to assess the anticoagulant effect of patients on Pradaxa®;

u. Inform physicians and laboratories that ECT results vary widely depending on the method used to perform the test;

v. Inform physicians and laboratories what method was used to perform ECT testing in the RE-LY trial;

w. Inform physicians that Pradaxa® Level testing has been available from LabCorp and/or Quest Diagnostics since at least 2013; and that virtually any laboratory in the U.S. could perform Pradaxa® Level testing if desired;

x. Provide adequate warnings regarding how to assess creatinine clearance, including warning physicians that estimated creatinine clearance results vary significantly depending on which formula is used and that the Cockcroft formula used with respect to the U.S. Pradaxa® Label is unreliable;

y. Provide adequate warnings regarding the increased risk of major gastrointestinal bleeds, particularly that Pradaxa® patients with mild kidney impairment have three times (300%) greater risks of suffering major gastrointestinal bleeds than warfarin patients (especially patients with a prior history of gastrointestinal issues);

z. Provide adequate warnings that approximately 95% of orally ingested Pradaxa® is metabolized to its active ingredient, dabigatran, in the gastrointestinal tract resulting in high exposure to an active anticoagulant in the gastrointestinal mucosal lining;

aa. Provide adequate warnings and information related to the large interpatient variability in trough Pradaxa® Levels (from 1 to over 1,000 ng/mL) seen in patients in the RE-LY trial;

bb. Inform physicians that the risk of patients suffering a major bleeding event doubled at a Pradaxa® Level of 210 ng/mL;

cc. Warn and instruct U.S. physicians how to appropriately assess renal function and/or to provide physicians with relevant and reliable information concerning renal function and Pradaxa® Levels; and

dd. Inform physicians about the impact of gender on Pradaxa® Levels.

81. Boehringer not only failed to warn, it affirmatively prevented dissemination of information by unethically influencing the medical and scientific literature to contort, bury, and hide information described in this Complaint, including, for example, deliberately removing a therapeutic Pradaxa® Level range and a cut off value to avoid an unnecessary risk of bleeding from the final, published version of the Reilly Lehr Paper, in order to conform the medical literature to Boehringer's "no monitoring" vision for Pradaxa®. This conduct included not only the hiring of "ghost-writers" but also Boehringer employees ghost-writing and influencing other publications to which no attribution of conflict of interest was given.

82. Hemoclot is a name branded test kit (reagent, calibrators, and controls) for diluted thrombin time that is approved by regulatory authorities outside the U.S. for assessing Pradaxa®

Levels. Boehringer represented to the company seeking U.S. approval for Hemoclot that Boehringer would partner with the company to help obtain Hemoclot approval by the FDA. However, when justification for a 200 ng/mL Pradaxa® Level was needed, Boehringer feared such analysis would lead to a monitoring requirement in contravention of Boehringer's "no monitoring" mantra and withheld the analysis from the Hemoclot company. Without the analysis form Boehringer, Hemoclot could not be approved by the FDA.

83. Pradaxa® was defective in design because Pradaxa® lacked both a reversal agent and a testing device for Pradaxa® Levels that Boehringer was capable of developing and/or having approved by the FDA prior to the time of Plaintiff's injuries. Boehringer failed to provide a reversal agent and/or testing device for Pradaxa® despite having multiple opportunities to do so, as established by:

a. Boehringer's Identification of the reversal agent and proof of concept for same before Pradaxa's® New Drug Application was even filed with FDA; and

b. Boehringer's "decision not to develop" a testing device for Pradaxa® in 2008 because such a testing device "would go against the 'no monitoring' idea/claim," despite Boehringer knowing about the relationship between the risk of bleeding and Pradaxa® Levels.

84. Neither Plaintiff nor Plaintiff's physicians received adequate warnings or information regarding the risks associated with the use of Pradaxa®. Plaintiff's physicians would not have prescribed Pradaxa® as they did, and Plaintiff would not have ingested Pradaxa® had Plaintiff and/or Plaintiff's physicians been aware of such risks.

85. Alternatively, had Boehringer properly warned or informed physicians, including Plaintiff's physicians, such physicians would have taken reasonable steps to insure Plaintiff's

Pradaxa® Levels were within the therapeutic range for Pradaxa® and/or would have switched Plaintiff to another anticoagulant to avoid such unnecessary risks.

86. Boehringer knew or should have known that consumers, such as Plaintiff, would needlessly suffer injury as a result of Boehringer's failures to warn of such risks.

87. For the reasons described above, Boehringer failed to provide timely and adequate warnings to physicians, pharmacies, and consumers, including Plaintiff and Plaintiff's physicians, regarding the true risks associated with the use of Pradaxa® to the detriment of Plaintiff.

Failure to Test/Study

88. Notwithstanding the plethora of data and analysis developed by Boehringer since Pradaxa's® approval, i.e., the newly acquired information, Boehringer has failed, neglected, and/or refused to perform adequate testing, study, and/or investigation as to why Pradaxa® patients suffer gastrointestinal bleeding on Pradaxa® at a rate significantly higher than warfarin and Eliquis (another NOAC medication) patients.

89. Boehringer failed to study and evaluate numerous P-gp inhibitors that are commonly prescribe to patients with atrial fibrillation, all of which put Pradaxa® patients at increased risk of bleeding by raising Pradaxa® Levels.

90. Boehringer has failed to study and evaluate data in its possession to adequately inform physicians how to initially dose Pradaxa® patients based on creatinine clearance estimates based on reliable formulas (MDMR, Cystatin-C and/or CKD-EPI).

91. Pradaxa® is defective because it was not accompanied by adequate warnings and information regarding its foreseeable dangers and/or the need to monitor for such danger. Boehringer could have reduced or avoided these risks with adequate warnings, and such omissions render Pradaxa® unreasonably dangerous and defective.

Plaintiff's Use of Pradaxa® and Resulting Injuries

92. Plaintiff was prescribed Pradaxa® on or around January 8, 2016 for treatment of atrial fibrillation.

93. Plaintiff suffered a major gastrointestinal bleed as a result of taking Pradaxa®. Plaintiff's bleeding event occurred on September 3, 2017, while taking Pradaxa®, which caused Plaintiff to be hospitalized at Howard Young Medical Center located in Woodruff, Wisconsin for a period of approximately three (3) days. Plaintiff's Pradaxa® use was permanently stopped as a result of his Pradaxa® bleed.

94. As a result of Boehringer's acts, omissions, and misrepresentations regarding the effectiveness, safety, and benefits of Pradaxa®, Plaintiff and Plaintiff's physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Plaintiff would be exposed to:

a. Unnecessary bleed risk as a result of excessive anticoagulation;

b. Excessive and/or uncontrollable bleeding;

c. Three (3) time (300%) higher risk of major gastrointestinal bleeding from Pradaxa® than from warfarin; and

d. The other risks and injuries described herein.

95. Therefore, Plaintiff was prescribed Pradaxa® as set forth herein. Pradaxa® was a cause and/or contributing factor in bringing about Plaintiff's injuries. Plaintiff experienced major and/or life-threatening bleeding which was caused and/or worsened as a result of Defendant's wrongful conduct. Plaintiff endured pain and suffering during the course of treatment for such injuries.

96. Prior to Plaintiff's use of Pradaxa®, Boehringer knew or should have known that the original and subsequent Pradaxa® Labels failed to adequately warn Plaintiff or Plaintiff's physicians of the risks associated with using Pradaxa® as described above, making it necessary that physicians know the need to:

a. Assess Plasma levels in order to avoid excessive anticoagulation;

b. Attain therapeutic Plasma Levels;

c. Understand the risks posed by certain personal characteristics, e.g., age, renal function, gender, weight;

d. Understand the risks posed by certain co-medications, e.g., p-gp inhibitors;

e. Understand the other risks identified herein, including but not limited to, patients with preexisting conditions and characteristics that put them at increased risk of bleeding on Pradaxa®; and

f. Understand that gastrointestinal injury is a known side effect of Pradaxa®.

97. Prior to Plaintiff's use of Pradaxa®, Defendant knew or should have known of the defective nature of Pradaxa®, and that persons taking Pradaxa® for even a brief period of time, including Plaintiff, were at increased risk for developing major or life-threatening bleeds. Defendant, through misrepresentations and omissions, concealed from Plaintiff and Plaintiff's physicians the true and significant risks associated with Pradaxa® use.

98. Had Plaintiff and/or Plaintiff's physicians known of the extent of the risks and dangers associated with Pradaxa®, as well as the lack of additional benefits, Plaintiff would not have been prescribed Pradaxa® and/or would not have taken Pradaxa® as he did, or, had Defendant provided adequate warnings and instructions regarding: a) the need to measure the Plasma Levels, b) additional risk factors such as age, renal function, gender,

weight, concomitant medications and prior GI ailments, then Plaintiff and Plaintiff's physicians would have altered the manner in which Pradaxa® was prescribed and taken.

99. As a direct and proximate result of using Pradaxa®, Plaintiff suffered major bleeding and/or uncontrollable and prolonged bleeding, and other injuries.

100. Pradaxa® was the legal cause of Plaintiff's injuries.

FIRST CAUSE OF ACTION
[Product Liability – Failure to Warn]

101. Plaintiff hereby incorporates by reference as if fully set forth herein, each and every allegation contained in all paragraphs above.

102. Defendant has engaged in the business of selling, distributing, supplying, manufacturing, marketing, and/or promoting Pradaxa®, and through that conduct has knowingly and intentionally placed Pradaxa® into the stream of commerce with full knowledge that it reaches consumers such as Plaintiff who ingested it.

103. Defendant did in fact sell, distribute, supply, manufacture, and/or promote Pradaxa® to Plaintiff and to his physicians. Additionally, Defendant expected the Pradaxa® that it was selling, distributing, supplying, manufacturing, and/or promoting to reach–and Pradaxa® did in fact reach – prescribing physicians and consumers, including Plaintiff and his physicians, without any substantial change in the condition of the product from when it was initially distributed by Defendant.

104. At all times herein mentioned, the aforesaid product was defective and unsafe in manufacture such that it was unreasonably dangerous to the user, and was so at the time it was distributed by Defendant and ingested by Plaintiff. The defective condition of Pradaxa® was due in part to the fact that it was not accompanied by proper warnings

regarding the possible side effect of developing severe bleeding as a result of its use and/or how to avoid the unnecessary risk of bleeding.

105. This defect caused serious injury to Plaintiff, who used Pradaxa® in its intended and foreseeable manner.

106. At all times herein mentioned, Defendant had a duty to properly design, manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings, and take such steps to assure that the product did not cause users to suffer from unreasonable and dangerous side effects.

107. Defendant so negligently and recklessly labeled, distributed, and promoted the aforesaid product that it was dangerous and unsafe for the use and purpose for which it was intended.

108. Defendant was aware of the probable consequences of the aforesaid conduct. Despite the fact that Defendant knew or should have known that Pradaxa® caused serious injuries, it failed to exercise reasonable care to warn of the dangerous side effect of developing severe bleeding from Pradaxa® use, even though this side effect was known or reasonably scientifically knowable at the time of distribution. Defendant willfully and deliberately failed to avoid the consequences associated with its failure to warn, and in doing so, Defendant acted with a conscious disregard for the safety of Plaintiff.

109. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care and, accordingly, Defendant had no reason to believe that Plaintiff would realize the danger of Pradaxa®.

110. Defendant, as the manufacturer and/or distributor of the subject product, is held to the level of knowledge of an expert in the field.

111. Plaintiff reasonably relied upon the skill, superior knowledge, and judgment of Defendant.

112. Had Defendant properly disclosed the risks associated with Pradaxa®, Plaintiff would have avoided the risk of severe bleeding by either not using Pradaxa® at all or by closely monitoring his blood levels to see if the drug was adversely affecting him.

113. As a direct and proximate result of the acts and omissions of Defendant alleged herein, including, but not limited to Defendant's failure to warn, and in such other ways as may be later shown, Pradaxa® caused Plaintiff to sustain injuries as herein alleged.

SECOND CAUSE OF ACTION
[Negligence/Gross Negligence]

114. Plaintiff hereby incorporates by reference as if fully set forth herein, each and every allegation contained in all paragraphs above.

115. At all times material hereto, Defendant, as a pharmaceutical company, had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Pradaxa®.

116. At all times material hereto, Defendant knew or should have known that Pradaxa® was inherently dangerous with respect to the risk of severe bleeding and the need to monitor Pradaxa® patients, including Plaintiff, due to the dangers Defendant knew or should have known Pradaxa® presented.

117. Defendant breached its duty of reasonable care to Plaintiff in that it was negligent and/or grossly negligent in its promotion, marketing, distribution, and labeling of Pradaxa®.

118. At all times material hereto, Defendant knew and willfully, wantonly, and/or recklessly disregarded the fact that Pradaxa® causes severe bleeding and that patients' blood levels should be closely monitored due to the risk of such bleeding.

119. Notwithstanding the foregoing, Defendant continued to aggressively market Pradaxa® to consumers, including Plaintiff herein, without disclosing the same and/or by intentionally, willfully, and wantonly misrepresenting and/or concealing the risks of Pradaxa® and the need to monitor for such dangers.

120. Defendant knew of Pradaxa®'s lack of warnings regarding the risk of severe bleeding and that patients' blood levels should be closely monitored due to the risk of such bleeding, but it intentionally concealed and/or willfully, wantonly, and/or recklessly failed to disclose the same and continued to market, distribute, and sell Pradaxa® without said warnings so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff herein, in conscious and willful disregard of the foreseeable harm caused by Pradaxa®.

121. Defendant's negligent, willful, wanton, and/or reckless failure to disclose information deprived Plaintiff and Plaintiff's physicians of necessary information to enable them to weigh the true risks of using Pradaxa® against its benefits.

122. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness, negligence, and/or gross negligence of Defendant, including, but not limited to, one or more of the following particulars:

a. In Defendant's design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Pradaxa®;

b. In Defendant's failure to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Pradaxa®'s dangerous and defective characteristics;

c. In Defendant's design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Pradaxa® as described hereinabove;

d. In Defendant's promotion and marketing of Pradaxa® in an overly aggressive, deceitful, and fraudulent manner, despite knowledge and evidence as to the product's defective and dangerous characteristics due to its propensity to cause severe bleeding;

e. In Defendant representing that Pradaxa® was safe for its intended use when, in fact, Pradaxa® was unsafe for its intended use;

f. In Defendant failing to perform appropriate post-market surveillance of Pradaxa®;

g. In Defendant failing to adequately and properly test Pradaxa® before and after placing it on the market;

h. In Defendant failing to conduct sufficient testing on Pradaxa® which, if properly performed, would have shown that Pradaxa® had the serious side effect of causing severe bleeding;

i. In Defendant failing to adequately warn Plaintiff and his physicians that the use of Pradaxa® carried a risk of developing severe bleeding and that patients' blood levels need to be monitored to lower the risk of such bleeding;

j. In Defendant failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of severe bleeding associated with the use of Pradaxa®;

k. In Defendant failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely severe bleeding, from Pradaxa® ingestion as described herein; and

l. In Defendant failing to perform appropriate pre-market testing of Pradaxa®;

123. Defendant knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendant's failure to exercise reasonable and ordinary care. Despite this knowledge, Defendant, in the pursuit of profits over the safety and well-being of patients, negligently and willfully and wantonly acted and/or failed to act as described herein.

124. As a direct and proximate result of Defendant's willful, wanton, and/or reckless, disregard for the rights and safety of its consumers, Plaintiff suffered severe physical and emotional injuries, including, but not limited to, severe gastrointestinal bleeds. Moreover, Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and may continue to incur such expenses in the future.

125. As a direct and proximate result of Defendant's carelessness, negligence, gross negligence, and wanton recklessness, Plaintiff suffered the injuries alleged herein in addition to such other further damages as may be shown to have been sustained by Plaintiff.

THIRD CAUSE OF ACTION
[Product Liability – Breach of Implied Warranty]

126. Plaintiff hereby incorporates by reference as if fully set forth herein, each and every allegation contained in all paragraphs above.

127. At all times mentioned herein, Defendant manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and sold

Pradaxa®, and prior to the time that it was prescribed to Plaintiff, Defendant impliedly warranted to Plaintiff that Pradaxa® was of merchantable quality and safe and fit for the use for which it was intended.

128. Plaintiff, individually and through his physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendant.

129. Plaintiff was prescribed, purchased, and used Pradaxa® for its intended purpose.

130. Due to Defendant's wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with Pradaxa® until after he used and suffered injury as a result of it.

131. Contrary to the implied warranty for the subject product, Pradaxa® was not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

132. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff suffered the injuries alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief on the entire Complaint, as follows:

a. Trial by jury;

b. Judgment for Plaintiff and against Defendant on all causes of action for actual and other compensatory damages, including, but not limited to, emotional distress, as a jury may determine appropriate;

c. Punitive damages in amount which is reasonably and rationally related to the egregiousness of Defendant's conduct, and which is in the public interest;

d. Attorney's Fees, Costs, and Pre and Post-judgment interest in accordance with Wisconsin law; and

e. Such other relief the Court deems as just and appropriate.

Respectfully submitted this 4th day of May, 2020.

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